

September 1, 1978

**78-48 MEMORANDUM OPINION FOR THE CHIEF,
TORTS SECTION, CIVIL DIVISION**

**Trade Secrets—Federal Food, Drug, and Cosmetic Act
(21 U.S.C. § 331)—Disclosure—Swine Influenza
Immunization Program (42 U.S.C. § 2746)**

This responds to your request for our opinion whether the Department may release to a court trade secret information entitled to protection under § 301 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(j), where the manufacturers owning the trade secrets consent to such release. The Department is defending certain personal injury and wrongful death actions arising out of the National Swine Influenza Immunization Program of 1976. *See* 90 Stat. 1114, 42 U.S.C. § 247b(k)(1)(A)(ii), which provides that the exclusive remedy under this program shall be against the United States. These actions have been consolidated for pretrial discovery purposes and are pending in the United States District Court of the District of Columbia. A relevant issue in the litigation will be the ingredients and manufacturing processes of the vaccine. The vaccine manufacturers claim that some of this information involves trade secrets.

The court has issued a protective order requiring that documents involved in this litigation be used for no other purpose. The order further provides that the documents or any information contained therein shall not be disclosed to anyone other than the attorneys and persons assisting them in litigation. Subject to the conditions in the protective order, the vaccine manufacturers have consented to use of the information in the litigation.

You ask whether the Department may, in light of § 301(j), release in discovery proceedings documents containing trade secret information acquired under the authority of the Federal Food, Drug, and Cosmetic Act. Section 301(j), 21 U.S.C. § 331(j), reads, in pertinent part, as follows:

The following acts and the causing thereof are hereby prohibited:

* * * * *

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of [the Department of Health, Education and Welfare] when relevant in any judicial proceeding under this Act, any information acquired under authority

of sections 404, 409, 505, 506, 507, 510, 512, 513, 514, 515, 516, 518, 519, 520, 704, 706, or 708 of this title concerning any method or process which as a trade secret is entitled to protection.

It is conceded that the pending judicial proceeding is not one under the Federal Food, Drug, and Cosmetic Act. However, we believe that the Department may release the documents in question in the pending litigation.

The intention of § 301(j) is solely to protect the manufacturers' interests in their trade secrets and it is tied to their interest of maintaining the protection to which the trade secrets are entitled. A manufacturer can waive his right to this protection. The legislative history of § 301(j) shows that it was designed as a "safeguard to the property rights of manufacturers by making [a crime] the unauthorized use or disclosure of any information. . . concerning any method or process which is entitled to protection in equity as a trade secret." S. Rept. No. 493, 73d Cong., 2d sess. 18, 21 (1934). This is consistent with the terms of § 301(j) barring disclosure of only the information relating to trade secrets that is "entitled to protection." Other than protecting the manufacturers' proprietary interest, there is no general societal value in keeping this information confidential.

As mentioned above, § 301(j) only bars disclosure of such trade secrets information as is "entitled to protection." This entitlement runs to the owner of the trade secret who may waive it entirely or in part. *See, Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470 (1974); *Underwater Storage, Inc. v. United States Rubber Co.*, 371 F. (2d) 950 (D.C. Cir. 1966), cert. denied, 386 U.S. 911 (1967). Thus, the "entitled to protection" element of § 301(j) is determined by the intent and legitimate interests of the owner of a covered trade secret. Accordingly, the owner may consent to a limited waiver in the pending litigation, thereby permitting the disclosure of the information to be used therein. *Cf., Plastic & Metal Fabrications, Inc. v. Roy*, 163 Conn. 257, 303 A. 2d 725 (1972). This comports with the literal language and the spirit of § 301(j).

For these reasons the Department may properly release the above-described documents in the pending litigation.

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